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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,873	04/18/2001	David K. Ho	208250	8939

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EXAMINER

KIFLE, BRUCK

ART UNIT	PAPER NUMBER
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1624

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DATE MAILED: 09/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,873

Applicant(s)

Ho et al.

Examiner

Bruck Kifle, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 8, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-106 is/are pending in the application.
- 4a) Of the above, claim(s) 92-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Election/Restriction

Applicant's election with traverse of group I and the species wherein A is Gelanamycin, B₁-B₂ is -NH-(CH₂)₃-NH-C(O)-(CH₂)₃- and X is L-cysteine, in Paper No. 9 is acknowledged. The traversal is on the ground that the claims have in common a special technical feature. This is not found persuasive because the claims do not have a special technical feature which is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. The feature is, thus, not special if it is known. That what is common here is the 2,5-dihydro-2,5-dioxo pyrrolidinyl which is known (see for example US 5,606,030).

Applicants arguments regarding group II is persuasive and, in fact, since compounds, corresponding compositions, a method of use and a process of making that are of the same scope are considered to form a single inventive concept under PCT Rule 13.1, 37 CFR 1.475(d), claims 61-91 reading on geldanamycin will be examined. The species of the compound in claim 63 are not so linked as to form a single inventive concept. The compounds are so diverse in scope that a prior art anticipating one compound under 35 USC 102 would not render obvious another compound of the same claim under 35 USC 103.

Claims 92-106 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group.

The requirement is still deemed proper and is therefore made FINAL.

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Improper Markush Rejection

Claims 61-91 are rejected as being drawn to an improper Markush group, that is, the claims lack unity of invention. The variable A is defined in such a way that it keeps changing the core of the compound that determines the classification. By changing the value of A, several patentably distinct and independent compounds are claimed. In order to have unity of invention the compounds must have "a community of chemical or physical characteristics" which justify their inclusion in a common group, and that such inclusion is not repugnant to principles of scientific classification" In re JONES (CCPA) 74 USPQ 149 (see footnote 2). The structural formula of the compound in claim 63 does not have a significant structural feature that is shared by all of its alternatives which is inventive. The structure has only a dioxopyrrolidindione as common. This feature is not inventive. Compounds embraced by the compound of claim 63 are so diverse in nature that a prior art anticipating a claim with respect to one member under 35 USC 102 would not render obvious the same claim under 35 USC 103. This is evidentiary of patentably distinct and independent inventions.

Limiting the claims to the elected geldanamycin would overcome this rejection.

Claim Rejections - 35 USC § 112

Claims 61-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The nature of the spacer moiety and the polar moiety in claim 63 is not known. One skilled in the art cannot say what is permitted and what is not.

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Claims 77-80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims are drawn to the treatment of cancer. The specification does not provide enablement for the treatment of cancer generally. No compound has ever been found that can treat cancers generally even though massive efforts have been directed towards this end. Since this assertion is contrary to what is known in oncology, proof must be provided that this revolutionary assertion has merits. Nearly all anticancer drugs are effective against only a limited group of related cancers. Therefore, a compound effective against cancer generally would be a revolutionary exception. Applicant is asserting that he succeeded where others have failed. Where extensive efforts have all failed, it is reasonable for the Patent and Trademark Office to require proof that the claimed invention actually works for this specific utility. It is well established that a utility rejection is proper when scope of enablement is not reasonably correlated to the scope of the claims. (In re Vaack 20 USPQ2d 1439, 1444, In re Ferens 163 USPQ 609).

In re Buting 163 USPQ 689 establishes that even clinical tests showing that a compound found to be useful in the treatment of two types of cancers was not sufficient for a much broader range.


The claims have been examined to the extent wherein A represents geldanamycin.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

September 5, 2002


Bruck Kifle
Primary Examiner
Art Unit 1624